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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,645	04/05/2001	Yao Xiong Hu	146-1-002	5717

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EXAMINER

SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 02/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/828,645

Applicant(s)
Yao Xiong Hu

Examiner
A. R. SALMI

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 30, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2, 6 6) ☐ Other:

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DETAILED ACTION

Claims 1-18 are pending.

Raw Sequence Listing have been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

Election/Restriction

Applicant's election with traverse of Group II (claims 7-18, and SEQ ID NO: 1) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that under the Patent policy the restriction requirement to one sequence is improper. This is not found persuasive because, in the first fold the selection was not selection of species, since it was explicitly indicated that the polypeptide are considered independent and patentably distinct (see the previous action page 3). Applicant does not traverse the argument set forth by the Office that their polypeptides are distinct one from the other and would support separate patents. Still further, the "up to 10 sequences" were directed to nucleic acids and not polypeptide. The search for this case is considered to be highly burdensome, the adequate search has to be conducted in both in-house and commercial databases. The information in databases almost double every few months, the office resources are now stretched to the limit, so only the selected sequence will be searched. Still further, the polypeptides are considered to be distinct invention which applicant does not argue.

The requirement is still deemed proper and is therefore made FINAL.

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The claims have been examined only to the extent of selected polypeptide designated as SEQ ID NO: 1. Applicants are requested to amend the claims accordingly by canceling the non-elected polypeptide. Claims 7-18 are considered.

Applicant is reminded to cancel the claims to the non elected claims.

Drawings

The drawings submitted on 4/5/2001 have been accepted by the Draftsman .

Claim Rejections - 35 USC § 112

Claims 7-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague and indefinite, the intended metes and bounds of the peptide is not defined. In addition, The term "derived" in claim 7 is a relative term, which renders the claim indefinite. The term "derived" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This affects the dependent claims.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP

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§ 2172.01. The omitted element(s) is/ are: the antigenic polypeptide that is needed for the method to function is not defined.

Claim 9 is confusing, since it's not clear which portion is suppose to be carboxyl region. The peptide of claim 8 is a short polypeptide and there is no teaching as to which region forms the carboxyl region and which region is N-terminus region.

Claim 10 is vague and indefinite for recitation of "infection", the method is suppose to detect antibodies of HPV in serum, the method says nothing about the infection. The method does not show how to detect the "virus", but rather the antibodies that are formed. A patient may have the antibodies without being infected. The claim has been interpreted in light of the specification, and since the specification does not set forth any method steps of detecting "infection" of the papillomavirus the claim is considered to be vague and indefinite.

In addition, Claims 10-13 are confusing, because it is not clear what is binding in the sample, and it is not clear how binding of something to a peptide antigen indicates the presence of virus and associated disease. The peptides are detecting antibodies, which indicates that the subject was exposed to human papilloma virus (HPV) and/or papillomavirus associated diseases, but does not necessarily mean that HPV is present, or that a disease state exists.

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Claims 11-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The parent claim is suppose to detect antibodies in serum which react with polypeptide of SEQ ID NO: 1. No diagnosis of cervical carcinoma, uterine cervix or epithelial cell abnormality is neither present or taught.

The term "derived" in claims 14-16 is a relative term, which renders the claim indefinite. The term "derived" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 14-18 are rejected under 35 U.S.C. 102(b) as anticipated by Schoolnik et al (US Patent No.4,777,239) .

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Schoolnik et al taught in the body of the patent regarding the use of human papillomavirus (HPV) peptide in a diagnostic assay (see column 4, lines 53-57, and column 9, lines 59-68), tissue type (see column 10, lines 14-18), and with respect to HPV E2, E6, E7 protein (see claim 1). Therefore, the teaching and the claims anticipate the claimed invention.

Claims 7, 14-18 are rejected under 35 U.S.C. 102(b) as anticipated by Breitburd et al (WO 8701375, 1987).

Breitburd et al anticipates the claims, since they taught the use of E7, E6 peptides for *in vitro* diagnostic assay to determine infection in a sample. In addition they taught raising antibodies against the peptides (see all the claims).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth

in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dillner et al (WO 91/18294).

The claims and disclosure of the above cited patent meets the broad limitations of the claimed invention as recited in claims 7, 14-18. Dillner et al disclosed a method of detecting the presence of human papillomavirus (HPV) utilizing polypeptide wherein the peptides are derived from various regions of papillomavirus for detecting the immune, including, cervix cancer and carcinoma (see the abstract, and claims 1-9). Alternatively, one of ordinary skill in the art at the time of filing would have been highly motivated by the teaching of Dillner et al to delete one amino acid from the sequence already taught by Dillner et al (see page 38, line 5), which reads on the SEQ ID NO: 1 of the applicant and only differs by one amino acid, to be utilized in a detection assays for detection of serum antibodies against papillomavirus antigen. One of ordinary skill in the art being familiar with the above cited art would not have anticipated any unexpected results, and none have been provided. The cited art taught the peptide as well as a method of detecting. Hence, the invention as a whole is prima facie obvious absent any unexpected results.

No claims are allowed.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

2/10/2003

Ans
ALI R. SALIMI
PRIMARY EXAMINER